**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/XYZ

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| **PRODUCT** | COSATRIM DS TABLETS | | REF. NO: NDQA201509397 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each tablet contains: Sulfamethoxazole BP 800 mg and Trimethoprim BP 160 mg | |
| **BATCH NO.:** 40399 | **PRESENTATION:** | White coloured, oval shaped, biconvex faced tablets, single scored on one face and embossed "COSATRIM DS" on the opposite unscored face, packed in blister strips of 10 tablets each and such 10 strips in a unit box. | |
| **MGF. DATE:** Sep. 2014 | **MANUFACTURER:** | COSMOS Limited | |
| **EXP. DATE:** Aug. 2019 | **ADDRESS:** | Rangwe Rd; Off Lunga Lunga Road P.O. Box 41433 - 00100, Nairobi, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| COT/06/11.03.2015/00095 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight:Weight | BP 2012 Vol. IV App XII C | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 5399 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 4.1 and 7.8 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC:HPLC | USP 38 NF 33 Page 5399 | :No tablet is less than 75% | SULPHAMETHOXAZOLE 98.1% (RSD = 1.1%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC | USP 38 NF 33 Page 5399 | :No tablet is less than 75% | TRIMETHOPRIM 97.7% (RSD = 1.0%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | SULPHAMETHOXAZOLE 98.3% (RSD = 0.2%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | TRIMETHOPRIM 96.6% (RSD = 0.2%; n=9) | **COMPLIES:COMPLIES** |

**CONCLUSION:** The product complies with the specifications for the tests performed.

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| ANALYST: | LORNA WANGARI |  | DATE:15-01-2016 |
| REVIEWER: | DR. E. TANUI |  | DATE:15-01-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:01-20-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-25-2016 |